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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,915	01/10/2006	Konsei Shino	P29144	5640
7055 7590 03/06/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/06/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,915	SHINO, KONSEI	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2007 and 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

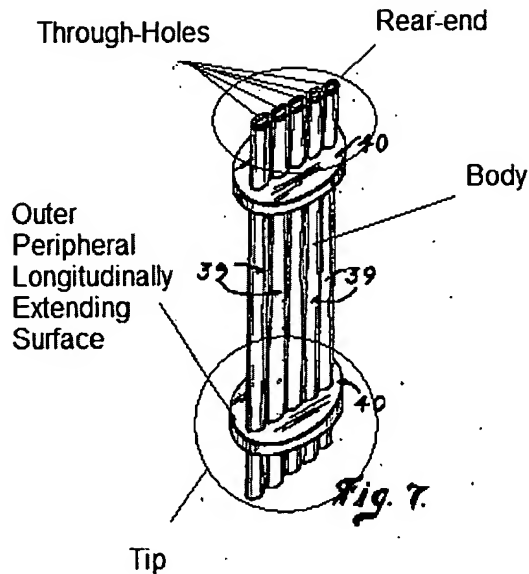
Claims 1, 3 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hipps et al. (US Pat. 2,543,780).

Hipps et al. disclose a device for ligament reconstruction comprising: a tip (Fig. 7 below) and body (Fig. 7 below) each having two parallel through-holes (Fig. 7 below) formed therein in juxtaposition, wherein said body is connected to an outer peripheral longitudinal extending surface (Fig. 7, ref. 40) of said tip; and a rear-end having two rear-end through-holes (Fig. 7 below) formed therein in juxtaposition coaxially with the two through-holes formed in said tip and body, wherein said tip and body has either one of a uniform generally elliptical or generally rectangular cross section elongated in a direction in which the through-holes thereof are juxtaposed (Fig. 7). Regarding the two parallel through-holes and the two rear-end through holes, two of the five through holes shown in Fig. 7 can be considered to be the parallel through holes and two of the through holes can be considered to be rear-end through holes. Regarding the tip and the body having a uniform general elliptical shape, the general shape of the outer periphery of both the body and the tip is uniform (Fig. 7) and can be considered to be generally elliptical (Fig. 7). The elliptical cross section is of a generally oval shape or a

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racetrack-like elliptical shape (Fig. 7). The ligament reconstruction is reconstruction of an anterior cruciate ligament.

The device of Hipps et al. is capable of performing a method for ligament reconstruction utilizing a ligament reconstruction device as recited in claim 1, the method comprising: drilling a single center guide pin into an articular bone and over-drilling the guide pin to a predetermined depth; drilling two guide pins into the bone parallel to the center guide pin and then removing the center guide pin; over-drilling the two guide pins; and driving the tip and body portion of the ligament reconstruction device into the articular bone from a cortex of the articular bone toward a ligament attachment portion inside a joint by hitting the rear end portion of the ligament reconstruction device to form a flat tunnel into which one end portion of ligament is to be inserted. The ligament is an anterior cruciate ligament with a bone piece. The ligament reconstruction is reconstruction of an anterior cruciate ligament, and the articular bone is a tibia.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipps et al. (US Pat. 2,543,780).

Hipps et al. disclose the claimed invention except for the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-

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like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from each other and each having a length of 4mm to 8mm; the rectangular cross section having a minor edge length of 3mm to 6mm and a major edge length of 7mm to 14mm; and the tip and body portion having a cross sectional area of 21mm² to 84mm².

With regard to claims 2 and 4-6, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Hipps et al. with the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from each other and each having a length of 4 to 8mm; the rectangular cross section having a minor edge length of 3 to 6mm and a major edge length of 7 to 14mm; and the tip and body portion has a cross sectional area of 21 to 84mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 01/03/2007 regarding the 35 U.S.C. § 102 and the 35 U.S.C. §103 rejections have been fully considered but they are not persuasive.

Applicant's arguments, see page 11 (argument regarding recitation of the *body being connected to an outer peripheral surface*), filed 01/03/2007, with respect to the

double patenting rejection of claim 1, have been fully considered and are persuasive.

The double patenting rejection of claim 1 has been withdrawn.

Furthermore, with regards to Applicant's statement that "... it appears that the Examiner intends to reject dependent claims 2, and 4-6 under 35 U.S.C. §103(a)," this is correct. As such, the rejections of claims 1, 3 and 7-10 under 35 U.S.C. §103(a) have been withdrawn.

With regards to Applicant's argument that the Hipps reference does not disclose the claimed elements of the amended claims, the Examiner respectfully disagrees. Please see the above rejections under 35 USC § 102 and 35 USC § 103.

With regards to Applicant's argument that the Hipps reference does not disclose the body portion being connected to an outer peripheral longitudinally extending surface of the tip, the Examiner respectfully disagrees. The body portion does not directly contact the outer peripheral longitudinally extending surface of the tip, but the components are connected, since the body is connected to ref. 40, which is connected to its outer periphery, which forms the longitudinally extending surface. Therefore, the body is connected to the peripheral longitudinally extending surface of the tip.

Applicant's arguments with regard to claims 2 and 4-6 do not overcome the rejections applied thereto, since applicant has not provided any convincing showing that these are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of

evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al. Regarding the axis/minor axis having a ratio of 2 to 5, the Applicant refers to this range as being preferable (page 5, lines 1-2), which indicates that this range is not critical, but preferable. Regarding the axis/minor axis having a ratio of 2 to 5, the Applicant refers to this range as being preferable (page 5, lines 1-2), which indicates that this range is not critical, but preferable. Regarding the parallel straight lines being spaced a distance of 3mm to 6mm from each other and each having a length of 4mm to 8mm, the Applicant refers to these ranges formed by these lines as being "preferably defined by a pair of parallel straight lines..." (page 5, lines 4-7), indicating that these ranges are not critical, but preferable. With regards to the rectangular cross section having a minor edge length of 3mm to 6mm and a major edge length of 7mm to 14mm, the Applicant also refers to these ranges as being preferable (page 5, lines 7-8), which also indicates that these ranges are not critical, but preferable. With regards to the tip and body portion having a cross sectional area of 21mm² to 84mm², the Applicant refers to this range as being preferable (page 5, lines 9-10), which indicates that this range is not critical, but preferable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

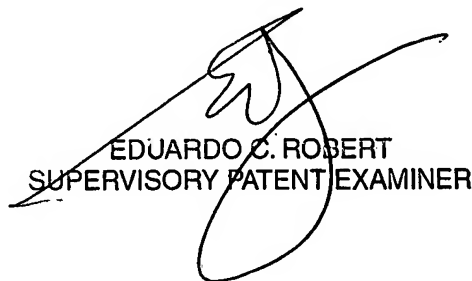
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

A handwritten signature consisting of the letters 'JLC' in a stylized, cursive script.A handwritten signature in black ink, appearing to be 'Eduardo C. Robert', written over the printed name.

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER